Translation

PCT/JP2003/016233

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 664192	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/016233	International filing date (*day/month/year*) 18 December 2003 (18.12.2003)	Priority date (*day/month/year*) 19 December 2002 (19.12.2002)
International Patent Classification (IPC) or national classification and IPC C12N 9/90, 9/99, 15/09, C12Q 1/533, C07D 401/06, G06F 17/30, 17/50, G01N 33/50		
Applicant RIKEN		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) Disc 1 , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 02 July 2004 (02.07.2004)	Date of completion of this report 03 March 2005 (03.03.2005)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/016233

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 6, 9

because:

☒ the said international application, or the said claims Nos. 6
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matter of claim 6 relates to a method for using space coordinates and corresponds to a mere presentation of information, which does not require an examination by the International Preliminary Examining Authority in accordance with PCT Article 17 (2)(a)(i) and Rule 39.1(v).

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 9
are so unclear that no meaningful opinion could be formed *(specify)*:

The substance described in claim 9 is specified by the "selection method described in claim 7 or 8" only, and can be any one of all the substances obtained by the said method. However, the specification states only one substance in claim 10 as the substance obtained by the said method. So, claim 9 is neither supported nor disclosed by the specification, and the description of claim 9 is very unclear.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 6, 9.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-3, 5, 8, 10	YES
	Claims	4, 7	NO
Inventive step (IS)	Claims	1-3, 10	YES
	Claims	4, 5, 7, 8	NO
Industrial applicability (IA)	Claims	1-5, 7, 8, 10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Proc. Natl. Acad. Sci. USA, 1999, Vol. 96, No. 2, pages 726-730
Document 2: JP, 2001-103869, A (Japan Science and Technology Corp., presently named Japan Science and Technology Agency), 17 April, 2001 (17.04.01)
Document 3: Biochim. Biophys. Acta, 2000, Vol. 1482, No. 1-2, pages 259-271
Document 4: Cell, 1997, Vol. 90, No. 6, pages 1085-1095
Document 5: JP, 2002-238553, A (Institute of Physical and Chemical Research, presently named RIKEN), 27 August, 2002 (27.08.02)
Document 6: EP, 1065213, A2 (Japan Tobacco Inc.), 27 August 2002 (27.08.02), & JP, 2001-69995, A

Claims 1-3

The subject matters of claims 1-3 appear to be novel and to involve an inventive step in view of documents 1-4 cited in the ISR.

Document 1 describes mouse-derived lipocalin-type prostaglandin D synthase (L-PGDS), and document 2 describes human-derived lipocalin-type prostaglandin D synthase (L-PGDS). Document 3 describes lipocalin-type prostaglandin D synthases (L-PGDS) derived from mouse, human and various other animals.

Furthermore, document 4 describes that hematopoietic prostaglandin D synthase (H-PGDS) was crystallized to decide its three-dimensional structure.

However, even if the method described in document 4 is used, the L-PGDS stated in any one of documents 1-3 cannot be crystallized. So, a novel method essentially different from the said method was used to allow the crystallization of lipocalin-type prostaglandin D synthase (L-PGDS) and the decision of its three-dimensional structure for the first time.

Claim 4

The subject matter of claim 4 does not appear to be novel or to involve an inventive step in view of documents 1 and 3 cited in the ISR.

Documents 1 and 3 respectively describe mouse-derived natural lipocalin-type prostaglandin D synthase (L-PGDS).

The lipocalin-type prostaglandin D synthase described in claim 4 cannot be distinguished from that described in document 1 or 3 as an enzyme.

Claim 5

The subject matter of claim 5 does not appear to involve an inventive step in view of documents 1 and 3 cited in the ISR.

Even after conversion into the Se-Met form of a natural enzyme described in document 1 or 3, the function as an enzyme is not substantially affected, and a person skilled in the art could have easily produced it.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: V

Claim 7

The subject matter of claim 7 does not appear to be novel or to involve an inventive step in view of documents 5 and 6 cited in the ISR.

Document 5 describes a virtual screening method, comprising the steps of processing the atom coordinates of enzymes by computer and searching drugs from a virtual compound library based on the obtained computer-processed information. Furthermore, document 6 describes a method for designing or identifying HCV polymerase inhibitors, comprising the steps of processing the atom coordinates of polypeptides having HCV polymerase activity by computer, and deciding the compatibility of test compounds with three-dimensional structure coordinates based on the obtained computer-processed information.

The present invention is an invention relating to computer software for information processing, and its technical feature is the information processing method used. An information processing method does not appear to be novel if the information processing procedure is not different from that in the prior art. In this invention, the matter of "three-dimensional structure coordinates" as a difference between the prior art and the present invention merely refers to the contents of data and does not change the information processing procedure by computer. So, this difference cannot be a ground for deciding that the subject matter of claim 7 of the present application appears to be novel.

Claim 8

The subject matter of claim 8 does not appear to involve an inventive step in view of documents 3, 5 and 6 cited in the ISR.

As also described in document 3, it is well known that lipocalin-type prostaglandin D synthase (L-PGDS) is an enzyme with prostaglandin H2 as a substrate. So, performing a wet experiment to confirm the result of the virtual screening described in claim 7 is considered to be a matter obvious to a person skilled in the art.

Meanwhile, with regard to the judgment as to the patentability of the present application, see "Examination Standard for Patents and Utility Models: Part VII Chapter 2 Biological Inventions; 7. Invention Cases Relating to the Three-dimensional Structures of Proteins" published on the homepage of Japan Patent Office.
(http://www.jpo.go.jp/shiryou/kijun/kijun2/pdf/tjkijun_vii-2.pdf)

Especially, with regard to claims 4 and 5, see Case 4, and with regard to claim 6, see Claim 1. Further, with regard to claims 7 and 8, see Case 5, and with regard to claim 9, see Case 9.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

In claim 1, the crystal of the enzyme is not sufficiently specified in description and is unclear.